UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF NEW YORK

CHRISTINA A. LANCASTER, et al.,

Plaintiffs,

-against-

1:19-CV-1377 (LEK/ML)

ETHICON, INC., et al.,

Defendants.

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Plaintiffs Christina and George Lancaster are among the thousands of plaintiffs who have sued defendants Ethicon, Inc. and Johnson & Johnson (together, "Defendants") for injuries caused by Defendants' allegedly defective pelvic mesh products. Two issues currently require the Court's attention. First, the parties have stipulated to dismissal twelve causes of action listed in the amended short form complaint. Dkt. No. 46 ("Stipulation"); see also Dkt. No. 4 ("Amended Short Form Complaint"). And second, Defendants move to exclude the opinions and testimony of one of Plaintiff's experts, Dr. Richard P. Marvel, M.D. ("Dr. Marvel"). Dkt. Nos. 44 ("Motion to Exclude"); 45 ("Motion Memorandum"); see also Dkt. No. 47 ("Opposition to Motion"); 48 ("Opposition Memorandum); 49 ("Reply Memorandum"). For the following reasons, the twelve causes of action are dismissed in accordance with the Stipulation and the Court grants in part and denies in part the Motion to Exclude.

II. BACKGROUND

This case is part of the massive products liability multi-district litigation ("MDL") against Defendants ongoing around the country. See In re Ethicon, Inc., Pelvic Repair System Products

<u>Liability Litigation</u>, No. 12-MD-2327. The product at issue is "transvaginal surgical mesh" used

primarily "to treat pelvic organ prolapse and stress urinary incontinence." <u>In re Ethicon, Inc.</u>

<u>Pelvic Repair Sys. Prod. Liab. Litig.</u>, No. 13-CV-12719, 2017 WL 6345880, at *1 (S.D.W. Va. Dec. 11, 2017).

The Court first describes the facts of the Lancasters' particular case, then lays out their case's procedural history. For the purposes of the instant motions, the relevant facts appear to be undisputed.

A. Facts

Christine Lancaster is a woman in her seventies who lives with her husband, George, in New York State. Dkt. No. 23 ("Plaintiff Profile Form"). On May 18, 2006, Mrs. Lancaster had surgery in which doctors implanted a Tension-free Vaginal Tape Obturator ("TVT-O")—manufactured by Defendants—in her pelvis. Id. at 2. The TVT-O implant was to treat stress urinary incontinence ("SUI") and Mrs. Lancaster's surgery was successfully completed without complications. Id.; Mot. Mem. at 2. The surgery took place at Bellevue Women's Hospital in Niskayuna, New York. Opp'n Mem. at 5.

However, after some time, Mrs. Lancaster started to experience new symptoms, including pelvic pain, vaginal pain, vaginal bleeding, and painful sexual intercourse (dyspareunia). Pl. Profile Form at 3. Plaintiffs attribute these symptoms to Defendants' defective transvaginal mesh. Opp'n Mem. at 5.

¹ Because Christine and George Lancaster share the same last name, the Court refers to them as Mrs. and Mr. Lancaster, respectively.

² "The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra." <u>Edwards v. Ethicon, Inc.</u>, No. 12-CV-9972, 2014 WL 3361923, at *1 (S.D.W. Va. July 8, 2014)

In 2011, because of these symptoms, Mrs. Lancaster went to see Dr. Brian Murray.

Opp'n Mem. at 6; Mot. Mem. at 2. Dr. Murray found "mesh extrusion or erosion" in Mrs.

Lancaster's pelvis and recommended surgery to correct it. Opp'n Mem. at 6; Pl. Profile Form at 3. In April 2012, Mrs. Lancaster had a second surgery, this time to remove portions of the TVT-O. Opp'n Mem. at 6; Mot. Mem. at 2. This surgery was successful, though Mrs. Lancaster's SUI soon returned. Opp'n Mem. at 6; Mot. Mem. at 2–3. Because of this, in August 2012, Mrs. Lancaster had a third surgery in which doctors implanted mesh in her pelvis produced by a different manufacturer and not at issue in this case. Opp'n Mem. at 6; Mot. Mem. at 3.

B. Relevant Procedural History

In February 2012, all the cases related to the In re Ethicon, Inc., Pelvic Repair System

Products Liability Litigation, MDL No. 2327 were transferred to the District Court for the

Southern District of West Virginia (the "MDL court"). See In re: Am. Med. Sys., Inc., Pelvic

Repair Sys. Prod. Liab. Litig., 844 F. Supp. 2d 1359, 1361 (U.S. Jud. Pan. Mult. Lit. 2012). The

Honorable Joseph R. Goodwin, U.S. District Judge, continues to preside over the In re Ethicon

MDL in that district.

On January 23, 2013, Plaintiffs filed this lawsuit in the Southern District of West Virginia, Dkt. No. 1 ("Short Form Complaint"), amending their complaint soon after, Am. Short Form Compl. The case proceeded through discovery, and, on July 27, 2017, Plaintiffs named their expert witnesses, including four general causation experts and Dr. Marvel as their case-specific expert. Dkt. No. 47-5 ("Plaintiffs' Expert Witness Disclosures"). On that same date, Plaintiffs' produced to Defendants' Dr. Marvel's resume and expert report. See Opp'n to Mot. at 7; see also Dkt. Nos. 47-6 ("Marvel Report"); 47-7 ("Marvel Resume").

On October 16, 2017, Defendants moved for partial summary judgment. Dkt. Nos. 42 ("Summary Judgment Motion"); 43 ("Summary Judgment Memorandum"). However, on October 30, 2017, the parties jointly filed the Stipulation, which stated that Plaintiffs "did not intend to pursue the claims on which [Defendants] sought partial summary judgment." Stipulation ¶ 1. The parties then agreed to dismiss with prejudice twelve of the eighteen causes of action named in the Amended Short Form Complaint, and they agreed that Defendants' "Motion for Partial Summary Judgment [was] . . . moot." Stipulation ¶¶ 2–4.

During that same period, on October 23, 2017, Defendants filed their Motion to Exclude Dr. Marvel's testimony. Mot. to Exclude. Plaintiffs filed their Opposition Memorandum on November 6, 2017, and Defendants filed their Reply Memorandum on November 13, 2017. See Docket.

On October 30, 2019, Judge Goodwin ordered this case transferred to this Court, "the venue from which [it] arise[s]," for resolution. Dkt. No. 60 ("Transfer Order").

C. Dr. Marvel's Expert Report

Before turning to the merits, the Court summarizes Dr. Marvel's expert report. In preparing his report, Dr. Marvel reviewed Mrs. Lancaster's medical records and deposition. Marvel Report at 1. He described her medical history, noting that the initial surgery to implant the TVT-O was "uncomplicated" and discussing the symptoms that led to the 2012 surgery and "mesh excision." <u>Id.</u> at 1–2. Dr. Marvel then offered three opinions.

First, Dr. Marvel stated that "[t]o a reasonable degree of medical certainty, Ms.

Lancaster's pelvic complaints of partner dyspareunia and chronic pelvic pain were caused by the marked scarring, erosion caused by defects in [Defendants'] mesh product." <u>Id.</u> at 2. He described how he had "reviewed Ms. Lancaster's medical records, considered her pre-implant

medical and surgical history, and utilized [his] education, experience, and training in performing a differential diagnosis to rule out any other potential causes of Ms. Lancaster's injuries." <u>Id.</u> He then proceeded to explain how he had ruled out various other potential causes of Mrs. Lancaster's injuries. <u>Id.</u> at 2–3.

Second, Dr. Marvel opined Mrs. Lancaster was "at risk of recurrence of erosion in the near future." <u>Id.</u> at 2.

And third, Dr. Marvel concluded that "Ms. Lancaster's injuries would not have occurred with a native tissue repair, which was a reasonable and available alternative procedure" <u>Id.</u> at 3.

III. DISCUSSION

The Court addresses, in turn: (A) the choice of law issues in this case; (B) the stipulation of dismissal submitted by the parties; and (C) the motion to exclude.

A. Choice of Law

As a preliminary matter, the Court must determine which jurisdiction's law governs this case. It does so bearing in mind that orders previously issued by an MDL court should generally remain binding once an individual case is sent back to its home venue. See Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 428 (E.D.N.Y. 2011) ("[In an MDL,] the law of the case doctrine 'posits that when a court decides a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.") (quoting Arizona v. California, 460 U.S. 605, 618 (1983)).

"This case is based on diversity jurisdiction. Federal law thus controls procedural issues and state law controls substantive issues." <u>Sanchez v. Bos. Sci. Corp.</u>, No. 12-CV-5762, 2014 WL 202787, at *3 (S.D.W. Va. Jan. 17, 2014); <u>see also Jazini v. Nissan Motor Co.</u>, 148 F.3d 181, 183 (2d Cir. 1998) ("In diversity cases the federal courts generally apply state law in

deciding substantive questions and federal law in deciding procedural ones."). For procedural issues governed by federal law, the Court applies this circuit's "interpretations of federal law, not the constructions of federal law of the transferor circuit." Charles Schwab Corp. v. Bank of Am. Corp., 883 F.3d 68, 82 (2d Cir. 2018); see also Adams v. Bos. Sci. Corp., 177 F. Supp. 3d 959, 962 (S.D.W. Va. 2016) ("When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located."). And the MDL court previously ruled that, when determining which state's law should govern substantive issues, courts should look to the choice of law provisions in "the place where the plaintiff was implanted with the product." In re Ethicon, Inc., No. 12-MD-2327, 2014 WL 346717, at *7 (S.D.W. Va. Jan. 30, 2014).

Because Mrs. Lancaster's implant surgery took place in New York State, Opp'n Mem. at 5, New York choice of law rules apply. Defendants argue—and Plaintiffs do not dispute—that under New York choice of law rules, New York tort law applies to Plaintiffs' claims. See Summary Judgment Mem. at 2–3 ("[T]he laws of New York apply to the claims addressed in this motion because Plaintiffs . . . resided at all times in the State of New York, and Ms. Lancaster was implanted with the TVT-O in New York.") (citing Padula v. Lilarn Props. Corp., 644 N.E.2d 1001, 1002 (N.Y. 1994)) (other citations omitted). In the absence of any objection from Plaintiffs, and because all the significant contacts lie in the state of New York, see Padula, 644 N.E.2d at 1002 (describing how New York choice of law rules require a court to decide "what are the significant contacts and in which jurisdiction are they located"), the Court applies New York substantive law to Plaintiffs' claims.

B. Stipulation of Dismissal

Federal Rule of Civil Procedure 41(a)(1)(ii) provides that "an action may be dismissed by the plaintiff without order of court . . . by filing a stipulation of dismissal signed by all parties

who have appeared in the action." Fed. R. Civ. P. 41. "Such a stipulation immediately terminates the case, and does not require any judicial approval." Reagan v. Fox Navigation, LLC, No. 02-CV-627, 2005 WL 2001177, at *1 (D. Conn. Aug. 17, 2005).

Here, the parties jointly signed and filed the Stipulation, agreeing to dismiss with prejudice the following of Plaintiff's claims: Count II – Strict Liability – Manufacturing Defect; Count IV – Strict Liability – Defective Product; Count VI – Common Law Fraud; Count VII – Fraudulent Concealment; Count VIII – Constructive Fraud; Count IX – Negligent Misrepresentation; Count X – Negligent Infliction of Emotional Distress; Count XI – Breach of Express Warranty; Count XII – Breach of Implied Warranty; Count XIII – Violation of Consumer Protection Laws; Count XV – Unjust Enrichment; and Count XVIII – Discovery Rule and Tolling. Stipulation ¶ 2. Those claims are therefore dismissed. Additionally, Defendants' Summary Judgment Motion is denied as moot. Stipulation ¶ 4.

The following claims remain in Plaintiff's case: Count I – Negligence; Count III – Strict Liability – Failure to Warn; Count V – Strict Liability – Design Defect; Count XIV – Gross Negligence; Count XVI – Loss of Consortium; and Count XVII – Punitive Damages. Stipulation ¶ 5.

C. Motion to Exclude Expert Testimony

Defendants move to exclude three opinions found in Dr. Marvel's expert report: (a) Dr. Marvel's "opinion that 'Ms. Lancaster's pelvic complaints of partner dyspareunia and chronic pelvic pain were caused . . . by defects in the Gynecare mesh product' without specifying any design defect is insufficient under New York law and therefore not helpful to the factfinder," Mot. Mem. at 1; see also Reply Mem. at 1 ("Dr. Marvel fails to state what is wrong with TVT-O that caused Ms. Lancaster's alleged injuries, an absolute prerequisite under New York law.")

(internal quotation marks omitted); (b) Dr. Marvel's "opinion regarding 'native tissue repair' is both irrelevant and unreliable," Mot. Mem. at 1; and (c) Dr. Marvel's "opinion about Ms.

Lancaster's alleged risk of recurrent erosion is irrelevant, speculative and unreliable," <u>id.</u>

Defendants do not challenge Dr. Marvel's qualifications. <u>See generally</u> Mot. Mem.

The Court addresses: (1) the legal standard governing a motion to exclude expert testimony; and (2) Defendants' Motion to Exclude as to each of Dr. Marvel's three opinions.

1. Legal Standard

The admissibility of expert testimony is governed by Federal Rule of Evidence ("FRE") 702 and the framework laid out in <u>Daubert v. Merrell Dow Pharm.</u>, 509 U.S. 579 (1993) and its progeny. <u>See Lara v. Delta Int'l Mach. Corp.</u>, 174 F. Supp. 3d 719, 727 (E.D.N.Y. 2016). FRE 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In applying FRE 702, the district court must ensure that "an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." <u>Amorgianos v. Nat'l R.R. Passenger Corp.</u>, 303 F.3d 256, 265 (2d Cir. 2002) (citing <u>Daubert</u>, 509 U.S. at 597). "Thus, . . . the district court must make several determinations before allowing expert testimony: (1) whether the witness is qualified to be an expert; (2) whether the opinion is based upon reliable data and methodology; and (3) whether the expert's testimony on a particular issue will assist the trier of

fact." <u>Bee v. Novartis Pharm. Corp.</u>, 18 F. Supp. 3d 268, 300 (E.D.N.Y. 2014) (citing <u>Nimely v.</u> City of New York, 414 F.3d 381, 396–97 (2d Cir. 2005)).

Under <u>Daubert</u>, a court must first determine whether the expert is qualified to testify through her or his "knowledge, skill, experience, training, or education." <u>See Zaremba v. Gen.</u>

<u>Motors Corp.</u>, 360 F.3d 355, 360 (2d Cir. 2004) (stating that, where the witness lacked qualifications, an analysis of the remaining <u>Daubert</u> factors "seems almost superfluous"); <u>see also</u> Fed. R. Evid. 702. A court should look at the totality of the expert's qualifications in making this assessment. <u>See, e.g.</u>, <u>Rosco</u>, <u>Inc. v. Mirror Lite Co.</u>, 506 F. Supp. 2d 137, 144–45 (E.D.N.Y. 2007). Finally, the court must ensure that the expert will testify on subjects that are within her or his area of expertise. See Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 81 (2d Cir. 1997).

As for reliability, "the district court should consider the indicia of reliability identified in [FRE] 702, namely, (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony is the product of reliable principles and methods; and (3) that the witness has applied the principles and methods reliably to the facts of the case." <u>United States v. Williams</u>, 506 F.3d 151, 160 (2d Cir. 2007) (internal citation and quotation marks omitted). Additionally, <u>Daubert</u> "identified a number of factors bearing on reliability that district courts may consider," such as:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) a technique's known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation; and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community.

Amorgianos, 303 F.3d at 266 (internal citations and quotation marks omitted) (citing <u>Daubert</u>, 509 U.S. at 593–94). These criteria are illustrative, not a "definitive" checklist. <u>See Kumho Tire</u> <u>Co. v. Carmichael</u>, 526 U.S. 137, 151 (1999). Moreover, "in addition to these criteria for determining whether the methodology is reliable, [FRE] 702 also requires that there be a

sufficiently reliable connection between the methodology and the expert's conclusions for such conclusions to be admissible." <u>Bee</u>, 18 F. Supp. 3d at 301 (citing <u>Gen. Elec. Co. v. Joiner</u>, 522 U.S. 136, 146 (1997)).

With respect to whether the expert's testimony will assist the trier of fact, "[t]his condition goes primarily to relevance." <u>Daubert</u>, 509 U.S. at 591; <u>see also In re: Ethicon, Inc.</u>, No. 12-MD-2327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) ("[S]imply, relevance turns on whether the expert testimony relates to any issues in the case."). "The <u>Daubert court</u> described this consideration as one of 'fit,' requiring a 'valid scientific connection' between the subject matter of the expert's testimony and the factual issues to be determined by the jury." <u>In re Zyprexa Prod. Liab. Litig.</u>, 489 F. Supp. 2d 230, 283 (E.D.N.Y. 2007) (quoting <u>Daubert</u>, 509 U.S. at 591–92). Additionally, testimony that "usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it," <u>United States v. Bilzerian</u>, 926 F.2d 1285, 1294 (2d Cir. 1991), does not "aid the jury in making a decision"; rather, it "undertakes to tell the jury what result to reach," and thus "attempts to substitute the expert's judgment for the jury's," <u>United States v. Duncan</u>, 42 F.3d 97, 101 (2d Cir. 1994) (emphasis omitted).

If the proffered expert testimony satisfies the above three-part test under <u>Daubert</u> and FRE 702, a court must finally consider whether the testimony's "probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . ." Fed. R. Evid. 403; <u>accord Nimely</u>, 414 F.3d at 397. The proponent of the expert testimony bears the burden of establishing the admissibility of such testimony by a preponderance of the evidence. <u>See Daubert</u>, 509 U.S. at 592 n.10.

"Ultimately, whether expert testimony is admissible at trial is a question of law which rests squarely within the broad discretion of the trial judge." See Lara, 174 F. Supp. 3d at 727; see also Williams, 506 F.3d at 160 ("[T]he district court is the ultimate 'gatekeeper."). Thus, "[t]he standard governing the admissibility of expert testimony is liberal and flexible." Hilaire v. DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 234 (E.D.N.Y. 2014). However, despite this liberality and flexibility, the court's over-arching "gatekeeping" role requires that it "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the field." Kumho, 526 U.S. at 152. Overall though, "the rejection of expert testimony is the exception rather than the rule." Argonaut Ins. Co. v. Samsung Heavy Indus. Co., 929 F. Supp. 2d 159, 164 (N.D.N.Y. 2013).

- 2. Defendants' Motion to Exclude Dr. Marvel's three opinions
 - <u>a.</u> <u>Dr. Marvel's Opinion that "Defects" in Defendants' Mesh Caused Mrs.</u> <u>Lancaster's Injuries</u>

The Court addresses Defendants' arguments separately with regard to Plaintiffs' design defect causes of action and their other causes of action.

i. Causes of Action for Design Defect

Defendants' challenge Dr. Marvel's expert opinion on the basis that it is not helpful to the factfinder because Dr. Marvel has failed to connect Mrs. Lancaster's injuries to a defect in Defendant's pelvic mesh, "as required by New York law." Mot. Mem. at 4. With respect to Plaintiffs' design defect claims, the Court agrees with Defendants that Dr. Marvel's opinion is inadmissible.

To establish a prima facie case of design defect under New York law, "plaintiffs must establish that (1) the product as designed posed a substantial likelihood of harm; (2) it was

feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing her injury.³ Argonaut, 929 F. Supp. 2d at 171–72 (citing Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 108 (1983)). "Additionally, to establish a prima facie case, the plaintiff is required to show that the defectively designed product caused his injury and that the defect was the proximate cause of the injury." Voss, 59 N.Y.2d at 109; see also id. at 109–10 ("The tie which proximate cause is to provide in order to impose legal liability must be between the design defect of the product and the injury."). Causation has two components: general and specific. In re Mirena IUD Prod. Liab. Litig., 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016), aff'd, 713 F. App'x 11 (2d Cir. 2017). "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." In re Rezulin Prod., No. 00-CV-2843, 2004 WL 2884327, at *2 (S.D.N.Y. Dec. 10, 2004) ("General causation [asks whether] smoking cigarettes can cause lung cancer ... Specific, or individual, causation [asks whether] a specific plaintiff's lung cancer was caused by his smoking.").

Here, Plaintiffs offer Dr. Marvel's testimony to prove specific causation and the testimony of their four other named experts to prove general causation. See Opp'n Mem. at 11 ("Plaintiffs have identified four other general causation experts"); id. at 12 ("Dr. Marvel's expert report is admissible to prove the TVT-O was the specific cause of Plaintiff's injuries"). This latter quote illustrates the problem with Dr. Marvel's proffered testimony: his report fails to describe how a defect in the TVT-O caused Mrs. Lancaster's injuries, as opposed to the mere

³ The same elements apply regardless of whether a plaintiff brings a design defect claim under a negligence or a strict liability theory. <u>See Argonaut</u>, 929 F. Supp. 2d at 177 ("Although plaintiffs assert the design defect claim under theories of strict products liability and negligence, the same prima facie case is required under both theories.") (citing <u>Jarvis v. Ford Motor Co.</u>, 283 F.3d 33, 62–63 (2d Cir. 2002)).

presence of the TVT-O itself. Dr. Marvel states that "Ms. Lancaster's pelvic complaints were caused by the marked scarring[] [and] erosion caused by defects in [Defendants'] mesh product," Marvel Report at 2, but Dr. Marvel does not state what defect caused Mrs. Lancaster's scarring or erosion, or how the defect caused Mrs. Lancaster's injuries. Thus, Dr. Marvel's report fails to "tie" "the design defect of the product" to "the injury," as is necessary to establish a design defect claim under New York law. Voss, 59 N.Y.2d at 110; Gilks v. Olay Co., 30 F. Supp. 2d 438, 443 (S.D.N.Y. 1998) ("Mere use of the product and subsequent injury . . . are not a sufficient basis from which to infer causation."). For this reason, the Marvel Report does not address the specific issue—how a mesh *defect* caused Mrs. Lancaster's injuries—for which it has been offered as evidence and must be excluded as unhelpful. See Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 710 (S.D.W. Va. 2014) ("An expert's testimony must help the jury . . . 'to determine a fact in issue.'" (quoting Fed. R. Evid. 702)).

Additionally, the Court must also exclude Dr. Marvel's opinion because, despite Plaintiffs' claims to the contrary, Opp'n Mem. at 11, the opinion "does not rely on any 'general causation opinion' or, in fact, any of Plaintiffs' other experts." Reply Mem. at 2. Indeed, Dr. Marvel's report makes no mention of any of the general causation experts Plaintiffs have designated to help prove their case and contains no indications that Dr. Marvel is familiar with or has relied on any of those experts' reports. See Marvel Report. Further, Dr. Marvel states explicitly that he reviewed certain documents—medical records and depositions—in preparing his report, but does not state that he reviewed any of the relevant expert reports in this action. Id. In general, for her or his testimony to be admissible, "a specific causation expert must show general causation or rely on a reliable general causation opinion." In re Mirena IUD Prod. Liab. Litig., 169 F. Supp. 3d 396, 457 (S.D.N.Y. 2016). Here, where "Dr. [Marvel] has not relied on

[Plaintiffs' other] experts in forming his opinion . . . , nor has he offered a general causation opinion himself . . . , [his] specific causation opinions [are] without foundation and therefore inadmissible." 4 Id. at 457–58; see also In re Rezulin Prods. Liab. Litig., 441 F. Supp. 2d 567, 578 (S.D.N.Y. 2006) (excluding experts' specific causation opinions for failing to offer opinions as to general causation).

Plaintiffs further argue that it would be unfair to require Dr. Marvel to opine about defects in Defendants' mesh because the MDL court "repeatedly held that experts may not provide opinion testimony that . . . uses a legal term of art . . . [such as] 'defective.'" Opp'n Mem. at 12–13 (citing In re: Ethicon, 2016 WL 4536885, at *4) (other citations omitted). Of course, this Court defers to previous rulings of the MDL court, see Deutsch, 768 F. Supp. 2d at 428 ("Orders issued by a federal transferee court [in an MDL] remain binding if the case is sent back to the transferor court."), but the Court sees no obstacle to Dr. Marvel attributing Mrs. Lancaster's injuries to "features" or "characteristics" of Defendants' mesh rather than particular "defects." In this way, Dr. Marvel could describe what attribute of Defendants' mesh caused Mrs. Lancaster's injuries without straying toward the proscribed language. Thus, with respect to Plaintiffs' design defect claims, Dr. Marvel's report and testimony are inadmissible.

ii. Other Causes of Action

Not so, however, with Plaintiffs' other claims, such as failure to warn, loss of consortium, and punitive damages.

⁴ Nor can Dr. Marvel's differential diagnosis serve as the basis for a general causation opinion. See Byrd v. Janssen Pharm., Inc., 333 F. Supp. 3d 111, 131 (N.D.N.Y. 2018), appeal withdrawn, No. 18-3137, 2019 WL 1791403 (2d Cir. Jan. 24, 2019) ("[A] differential diagnosis . . . does not speak to the issue of general causation. [It] assumes that general causation has been proven") (alterations in original); In re: Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 178 (S.D.N.Y. 2009) ("[A] differential diagnosis generally is insufficient by itself to support an opinion on general causation").

In a failure-to-warn claim, the "defect" is the failure to warn itself. See Wickenden v. Saint-Gobain Performance Plastics Corp., No. 17-CV-1056, 2018 WL 3069193, at *6 (N.D.N.Y. June 21, 2018) (Kahn, J.) ("To state a prima facie case of liability on the basis of a defendant's failure to warn, the plaintiff must establish that . . . the manufacturer had a duty to warn [and] the manufacturer breached the duty to warn in a manner that rendered the product defective, i.e., reasonably certain to be dangerous ") (internal quotation marks omitted). Thus, Dr. Marvel's lack of specificity about the "defect" that caused Mrs. Lancaster's injuries is immaterial. See Marvel Report at 2. And Dr. Marvel's testimony will help the jury understand the nature and extent of Mrs. Lancaster's injuries, a necessary element of her failure-to-warn claim. See Wickenden, 2018 WL 3069193, at *6 ("[A] failure to warn . . . plaintiff must establish [that she] suffered loss or damage"). Further, Dr. Marvel's testimony about Mrs. Lancaster's injuries might bear on Plaintiffs' claim for punitive damages, see Romaine v. Rawson, 140 F. Supp. 2d 204, 214 (N.D.N.Y. 2001) (looking to "severity of [p]laintiff's injuries" in determining punitive damages award), and their claim for loss of consortium, see Hogan v. Cty. of Lewis, N.Y., No. 11-CV-0754, 2015 WL 1400496, at *16 (N.D.N.Y. Mar. 26, 2015) (noting that loss of consortium depends on "demonstrat[ing] a physical injury"), aff'd sub nom. Okudinani v. Rose, 779 F. App'x 768 (2d Cir. 2019). Dr. Marvel's opinion attributing Mrs. Lancaster's injuries to Defendants' mesh will thus be helpful to the jury as to these non-design-defect claims. So long as Dr. Marvel is qualified and the opinion is reliable, satisfying Daubert's other two requirements, the Court can admit Dr. Marvel's testimony as to Plaintiffs' other claims.

Although Defendants' have not challenged Dr. Marvel's qualifications, <u>see generally</u>

Mot. Mem.; Reply Mem., even if they had, the Court would find that Dr. Marvel is qualified. Dr.

Marvel is board certified in obstetrics and gynecology, and currently serves as Director of the

Center for Pelvic Pain at the Anne Arundel Medical Center in Annapolis, Maryland. Marvel Resume at 1, 6. He completed a residency in obstetrics and gynecology at Hahnemann University Hospital in Philadelphia, Pennsylvania, and has served as an assistant professor of gynecology and obstetrics for over fifteen years, including at the University of Maryland School of Medicine and the Johns Hopkins School of Medicine. Id. at 1. Moreover, he has published numerous articles, book chapters, and other media in his field. Id. at 1–3. Courts have found experts with similar qualifications qualified to testify. See, e.g., Edwards, 2014 WL 3361923, at *4–5 (ruling that expert obstetrician and gynecologist who served as "Director of the Division of Laparoscopy and Pelvic Pain at the University of North Carolina at Chapel Hill" and "teaches and studies the . . . causes of chronic pelvic pain . . . " was qualified to testify about the ways in which Defendants' mesh products cause pelvic injury).

As for reliability, here again Defendants have declined to challenge Dr. Marvel's opinion. See generally Mot. Mem. And again, even if they had, the Court would find that Dr. Marvel utilized a reliable methodology in forming his opinion. Dr. Marvel used a technique called differential diagnosis, Marvel Report at 2–3, "a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes," Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation marks omitted). "A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." Ellis v. Appleton Papers, Inc., No. 94-CV-558, 2006 WL 346417, at

*5 (N.D.N.Y. Feb. 14, 2006). "This technique has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." Id. For these reasons, it has also been accepted by the courts. See, e.g., McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1043–44 (2d Cir. 1995) (rejecting defendant's argument that differential diagnosis does not qualify as "scientific" under Daubert); Davids v. Novartis Pharm. Corp., 857 F. Supp. 2d 267, 278–79 (E.D.N.Y. 2012) (admitting expert's specific causation testimony based on differential diagnosis); see also Edwards, 2014 WL 3361923, at *3 ("A reliable differential diagnosis passes scrutiny under Daubert.").

Here, Dr. Marvel performed a reliable differential diagnosis: he "reviewed Mrs. Lancaster's medical records, including her pre-mesh implant history and post-implant complaints, and performed his own examination of her." Opp'n Mem. at 9 (citing Marvel Report at 2–3). Then, using his "education, experience, and training," he ruled out numerous potential non-mesh causes of Mrs. Lancaster's injuries. Marvel Report at 2–3. Such a differential diagnosis passes scrutiny under <u>Daubert</u>. Therefore, for the purposes of proving Plaintiffs' non-design-defect claims, the Court admits Dr. Marvel's opinion that Defendants' mesh implant caused Mrs. Lancaster's injuries.

<u>b.</u> <u>Dr. Marvel's Opinion that "Mrs. Lancaster's Injuries Would Not Have Occurred with a Native Tissue Repair"</u>

Defendants' argue that Dr. Marvel's "opinion regarding 'native tissue repair' is both irrelevant and unreliable." Mot. Mem. at 6–8. Though the Court is somewhat skeptical of several arguments advanced in Defendants' rather breathless briefing, see Mot. Mem. at 7 ("Dr. Marvel's incredible prediction that Ms. Lancaster's injuries would not have occurred if she had

undergone a native tissue repair[5] begs the question whether Dr. Marvel consulted a crystal ball to reach this conclusion.") (footnote added) (emphasis in original), Defendants are correct that "Plaintiffs ignore entirely Ethicon's argument [regarding] native tissue repair," Reply Mem. at 2; see generally Opp'n Mem. For this reason, the Court grants Defendants' Motion to exclude Dr. Marvel's opinion that "Ms. Lancaster's injuries would not have occurred with a native tissue repair." See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2327, 2016 WL 4500767, at *5 (S.D.W. Va. Aug. 26, 2016) (granting motion to exclude expert testimony where plaintiffs failed to respond to defendants' arguments in favor of exclusion).

c. Dr. Marvel's Opinion that Mrs. Lancaster "Is at Risk of Recurrence of Erosion in the Near Future"

Finally, Defendants argue that Dr. Marvel's "opinion about Ms. Lancaster's alleged risk of recurrent erosion is irrelevant, speculative and unreliable." Mot. Mem. at 1. They elaborate that Dr. Marvel "does not substantiate [t]his opinion . . . in the medical record, in scientific literature or anywhere else." Id. at 8. The Court agrees because "expert testimony should be excluded if it is speculative or conjectural." Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996). Dr. Marvel's report describes how, in April 2012, Mrs. Lancaster had surgery to remove part of Defendants' mesh sling, and how in August 2012 she had another surgery to implant a different mesh sling not at issue in this case. Marvel Report at 2. In light of these facts, Dr. Marvel's July 2017 opinion that Mrs. Lancaster "is at risk of recurrence of erosion in the near future" appears irrelevant and speculative. Id. The report contains no explanation of why, when Mrs. Lancaster had no complaints of symptoms associated with erosion—pelvic pain, dyspareunia, etc.—between the 2012 surgery to remove Defendants' mesh and 2017 when Dr.

⁵ The Court notes that Dr. Marvel attributes some of Mrs. Lancaster's injuries to *mesh* erosion. Marvel Report at 2–3.

Marvel prepared his report, she was at risk of suddenly experiencing those symptoms again. Nor does the report explain how Dr. Marvel can be sure that such symptoms would be attributable to the pieces of Defendants' mesh remaining in Mrs. Lancaster's pelvis and not Plaintiffs' replacement mesh sling. Because Dr. Marvel has failed to explain the facts, data, and scientific principles underlying his conclusion, his opinion that Mrs. Lancaster "is at risk of recurrence of erosion in the near future" is excluded. See Amorgianos, 303 F.3d at 267 ("[I]t is critical that an expert's analysis be reliable at every step . . . any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible.") (internal quotation marks omitted).

IV. CONCLUSION

Accordingly, it is hereby:

ORDERED, that, under the terms of the parties' stipulation of dismissal (Dkt. No. 46), the following causes of action are DISMISSED with prejudice from this case: Count II – Strict Liability – Manufacturing Defect; Count IV – Strict Liability – Defective Product; Count VI – Common Law Fraud; Count VII – Fraudulent Concealment; Count VIII – Constructive Fraud; Count IX – Negligent Misrepresentation; Count X – Negligent Infliction of Emotional Distress; Count XI – Breach of Express Warranty; Count XII – Breach of Implied Warranty; Count XIII – Violation of Consumer Protection Laws; Count XV – Unjust Enrichment; and Count XVIII – Discovery Rule and Tolling; and it is further

ORDERED, that the following claims may proceed: Count I – Negligence; Count III –

Strict Liability – Failure to Warn; Count V – Strict Liability – Design Defect; Count XIV –

Gross Negligence; Count XVI – Loss of Consortium; and Count XVII – Punitive Damages; and it is further

ORDERED, that, under the terms of the parties' stipulation of dismissal (Dkt. No. 46), Defendants' motion for partial summary judgment (Dkt. No. 42) is **DENIED** as moot; and it is further

ORDERED, that Defendants' motion to exclude the expert opinion and testimony of Dr. Richard Marvel (Dkt. No. 44) is GRANTED as to Dr. Marvel's opinions that: (1) plaintiff Christina Lancaster "is at risk of recurrence of erosion in the future"; (2) that her "injuries would not have occurred with a native tissue repair"; and (3) with respect only to Plaintiffs' design defect claims, that "Ms. Lancaster's pelvic complaints . . . were caused by . . . defects in [Defendants'] mesh product." The motion is otherwise **DENIED**; and it is further

ORDERED, that the Clerk serve a copy of this Decision and Order on all parties in accordance with the Local Rules.

IT IS SO ORDERED.

DATED: February <u>19</u>, 2020

Albany, New York

Lawrence E. Kahn

Senior U.S. District Judge